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IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, STATE
OF CONNECTICUT, and STATE OF NEW
YORK *ex rel.* [FILED UNDER SEAL],

Plaintiffs,

vs.

[FILED UNDER SEAL],

Defendants.

CASE NO.

**COMPLAINT FOR MONEY DAMAGES
AND CIVIL PENALTIES FOR
VIOLATIONS OF THE FALSE CLAIMS
ACT**

DEMAND FOR JURY TRIAL

**[FILED IN CAMERA AND UNDER SEAL
PURSUANT TO 31 U.S.C. § 3730(b)(2)]**

U.S. DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
SEP 17 2024

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, STATE
OF CONNECTICUT, and STATE OF NEW
YORK *ex rel.* Fraud Buster, LLC,

Plaintiffs,

vs.

ENZO BIOCHEM, INC., a corporation;
ELAZAR RABBANI, Ph.D., an individual;
HANSEN LEE, an individual; KARA
CANNON, an individual;

Defendants.

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Plaintiff UNITED STATES OF AMERICA (“United States”), by and through Relator Fraud Buster, LLC (“RELATOR”), allege as follows:

I. INTRODUCTION

1. Over the past several years, Enzo Clinical Labs, Inc. (“ENZO”), a publicly traded New York company, and three of the company’s executives (collectively, “DEFENDANTS”), have perpetrated a fraud on U.S. taxpayers through four independent schemes designed to defraud Medicare and other government payors including Medicaid and the Health Resources and Services Administration (“HRSA”). Each of DEFENDANTS’ schemes results in false claims for payment, which bills the government.

2. First, DEFENDANTS use an unauthorized and inappropriate diagnostic code to trigger payments for Covid-19 surveillance tests. In using this code DEFENDANTS falsely represent, for each patient receiving a surveillance test, that “there is a concern about a possible exposure to COVID-19, but this is ruled out after evaluation.” DEFENDANTS bill millions to Medicare/Medicaid each year for Covid-19 reimbursement.

3. Second, DEFENDANTS illegally limit patient co-payment and deductible obligations to only \$20 in order to “pull through” government payments. DEFENDANTS’ waiver of co-payments and deductibles enables ENZO to capture patients enrolled in Emblem-GHI, an insurance company with 3.4 million members in the New York Metropolitan area. Emblem-GHI has exclusive contracts for laboratory services with Quest Diagnostics and LabCorp, under which patient co-payments are \$50. ENZO’s waiver scheme facilitates the solicitation of Emblem-GHI insured patients from ENZO’s clients and allows ENZO to sell new clients since their patients would receive a 60% savings on co-payments by switching from Quest and LabCorp, the Emblem-GHI in-network labs. The routine waiver of deductibles and co-payments constitutes illegal

remuneration, and generates lucrative “pull-through” Medicare and other government insurance revenue. Moreover, this results in diminished restraints on whether tests are medically necessary, as costs are substantially reduced for patients due to the waivers.

4. Third, DEFENDANTS use the code for expedited Covid-19 tests even though DEFENDANTS fail to turn around test results within the required two calendar days.

5. Fourth, DEFENDANTS refuse to pass on to Connecticut Medicaid ENZO’s lowest charges to other payors, as required by Connecticut law.

6. This is a *qui tam* action for violation of the federal False Claims Act (31 U.S.C. § 3150 *et seq.*), as well as the New York False Claims Act and the Connecticut False Claims Act to recover treble damages, civil penalties and attorneys’ fees and costs for Plaintiffs and on behalf of the United States, and the states of New York and Connecticut for fraudulent billing of government insurers. Non-public information personally known to RELATOR serves as the basis for this action.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 31 U.S.C. sections 3730(b) and 3732(a), which confer jurisdiction on this Court for actions brought under the federal False Claims Act, and authorize nationwide service of process, as well as 28 U.S.C. section 1367. Venue is proper in this district pursuant to 31 U.S.C. section 3732(a), as all DEFENDANTS transact business in the state of New York and acts proscribed by 31 U.S.C. section 3729 occurred in the state of New York.

III. PARTIES

8. The plaintiffs in this action are UNITED STATES OF AMERICA, STATE OF CONNECTICUT, and STATE OF NEW YORK by and through Relator Fraud Buster, LLC.

9. RELATOR Fraud Buster, LLC is a Delaware limited liability company whose members are involved in the healthcare industry.

10. DEFENDANT ENZO BIOCHEM, INC. is a New York corporation with its principal place of business in New York, New York. The company was founded in 1976. ENZO is a public company that trades on the New York Stock Exchange under the ticker symbol “ENZ.” The company is an integrated diagnostics, clinical lab, and life sciences company that researches, develops, manufactures, and markets diagnostic and research products based on genetic engineering, biotechnology, and molecular biology. It operates a full-service clinical laboratory in Farmingdale, New York. There, ENZO services a network of thirty patient service centers in New York and New Jersey, along with free-standing “Stat” or rapid response laboratories in New York City and Connecticut, around thirty full-service phlebotomy centers, and an in-house logistics department. ENZO markets its products and services through its direct sales force and a network of distributors in the United States and internationally.

11. DEFENDANT ELAZAR RABBANI served as Chairman of the Board of Directors of ENZO since the Company’s founding in 1976 until January 2022. He served as ENZO’s CEO until October 18, 2021. ENZO’s website listed RABBANI as the Chief Scientific Officer until this year.

12. DEFENDANT HANSEN LEE is ENZO’s Director of Clinical Operations.

13. DEFENDANT KARA CANNON is ENZO’s Chief Operating Officer and previously served as ENZO’s Chief Commercialization Officer.

IV. STATUTORY BACKGROUND

14. The Federal False Claims Act (“FCA”), as amended by the Fraud Enforcement and Recovery Act of 2009, provides, in pertinent part, that a person is liable to the United States

government for three times the amount of damages the government sustains because of the act of that person, plus civil penalties, for each instance in which the person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(1)(1)(A).

15. The New York False Claims Act (“NYFCA”) provides, in pertinent part, that a person is liable to the state or local government for three times of the amount of all damages sustained, including consequential damages, for each instance in which a person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” N.Y. State Fin. Law § 189(1)(a), (b).

16. The Connecticut False Claims Act (“CTFCA”) provides, in pertinent part, that a person is liable to the state for three times the amount of all damages sustained, including the costs and investigation and prosecution of such violation, for each instance in which a person “knowingly present[s], or cause[s] to be presented, a false or fraudulent claim for payment or approval” or “[k]nowingly make[s], use[s] or cause[s] to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program.” Conn. Gen. Stat. § 4-275(a)(1), (2).

17. The FCA, NYFCA, and CTFCA each define the term “claim” to mean “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be drawn down or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government (i) provides or has provided any portion

of the money or property requested or demanded; or (ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.” 31 U.S.C. § 3729(b)(2)(A); N.Y. State Fin. Law § 188(1); Conn. Gen. Stat. § 4-274(1).

18. The FCA, NYFCA, and CTFCA each make a person liable to the government for three times the amount of damages which the government sustains because of the act of that person, plus a civil penalty, for each instance in which the person “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim”, or for each instance in which the person “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(1)(1)(G); N.Y. State Fin. Law § 189(1)(h); Conn. Gen. Stat. § 4-275(8).

19. The FCA, NYFCA, CTFCA each define the terms “knowing” and “knowingly” to mean that a person, with respect to information: (i) “has actual knowledge of the information”; (ii) “acts in deliberate ignorance of the truth or falsity of the information”; or (iii) “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A)(i)-(iii); N.Y. State Fin. Law § 188(3)(a)(i)-(iii); Conn. Gen. Stat. Ann. § 4-274(1). The FCA, NYFCA, CTFCA further provide that “no proof of specific intent to defraud” is required. 31 U.S.C. § 3729(b)(1)(B); N.Y. State Fin. Law § 188(3)(b); Conn. Gen. Stat. § 4-274(1).

V. DEFENDANTS KNOWINGLY VIOLATE THE FEDERAL AND NEW YORK FALSE CLAIMS ACTS

A. DEFENDANTS Improperly Use Diagnosis Codes for Surveillance Testing

20. DEFENDANTS engaged in acts of “code steering” by improperly adding inapplicable diagnosis codes to insurance claims that were not provided by the ordering physician or representative, so as to receive payment in connection with Covid-19 surveillance tests.

21. Codes associated with the International Classification of Disease, 9th and 10th

Editions, Clinical Modification (“ICD-9” and “ICD-10” codes) are used for the classification of disease and conditions, and to describe signs, symptoms, and medical circumstances. These codes are used to indicate the medical necessity of a particular test. Without appropriate diagnosis codes, Current Procedural Terminology (CPT) codes reported for reimbursement will not be paid. ICD-9/ICD-10 codes may only be supplied by the ordering physician or a representative of that physician.

22. It is illegal to use an inapplicable ICD-9/ICD-10 code for the purpose of causing or increasing payment for a test. Compliance guidance for clinical laboratories, issued by the Office of the Inspector General (“OIG”) in August of 1998, explains that using diagnosis codes not provided by a physician violates Medicare statutes and regulations:

Laboratories should not: (1) use information provided by the physician or other authorized individual from earlier dates of service (other than standing orders . . .); (2) create diagnosis information that has triggered reimbursement in the past; (3) use computer programs that automatically insert diagnosis codes without receipt of diagnostic information from the ordering physician or other authorized individual; or (4) *make up information for claim submission purposes*. Laboratories should: (1) contact the ordering physician, authorized person on the physician’s staff or other individual authorized to order tests to obtain information in the event that such information was not provided; and (2) accurately translate narrative diagnoses obtained from the physician or other authorized individual to ICD-9-CM codes.¹

23. Furthermore, in order to be considered for Medicare coverage, an item or service must fall within a statutory benefit category. Section 1862 of the Social Security Act excludes from any benefit category “items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. ¶ 1395y(a)(1)(A). Official guidance issued by the Centers for Medicare and

¹ 63 Fed. Reg. 45080, Aug. 24, 1998 (OIG Compliance Program Guidance for Clinical Laboratories) [attached as **Exhibit 1**] (emphasis added).

Medicaid Services indicate that asymptomatic screening is excluded from such coverage.²

24. DEFENDANTS established a robust screening program for numerous ENZO clients, including schools, universities, and other sites requesting Covid-19 surveillance testing.

25. DEFENDANTS routinely billed the government using an improper ICD-10 code to ensure payment.

26. The appropriate diagnosis code for such asymptomatic screening is Z11.59.³

27. Knowing that surveillance testing may not trigger payment from Medicare, Medicaid, HRSA, or other insurance payors, DEFENDANTS utilized an inappropriate code, Z03.818, which is applicable “where there is a concern about a possible exposure to COVID-19, but this is ruled out after evaluation.”⁴

28. Margaret McGuinness, a Field Service Manager for ENZO, observed DEFENDANT Hansen Lee, ENZO’s Director of Clinical Operations, directing Phlebotomy Manager, Elizabeth Newton and her staff to utilize ICD-10 code Z03.818, regardless of a patient’s circumstance. He repeated this policy frequently as a reminder to everyone working at the collection sites. In fact, Ms. McGuinness observed that the in-take screen on ENZO’s computer at screening sites where she worked only listed one diagnosis code available to select.

29. The ICD-10 code Z03.818—applicable only where a patient has had a “possible exposure to COVID-19 . . . ruled out after evaluation”—was clearly not appropriate for the

² U.S. Ctr. Medicare & Medicaid Svcs., *Medicare National Coverage Determinations Manual*, Rev. 11426 at 190.12 (May 20, 2022), available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part3.pdf (“Testing for asymptomatic bacteriuria as part of a prenatal evaluation may be medically appropriate but *is considered screening and therefore not covered by Medicare.*”) (emphasis added).

³ U.S. Ctr. Disease Control, ICD-10-CM Official Coding and Reporting Guidelines April 1, 2020 through September 30, 2020 [attached as **Exhibit 2**] (“For asymptomatic individuals who are being screened for COVID-19 and have no known exposure to the virus, and the test results are either unknown or negative, assign code Z11.59.”).

⁴ *Id.* (“For cases where there is a concern about a possible exposure to COVID-19, but this is ruled out after evaluation, assign code Z03.818, Encounter for observation for suspected exposure to other biological agents ruled out.”).

thousands of screening tests ENZO administered at educational facilities and other surveillance sites without knowledge or suspicion of patients' exposure to Covid-19, or whether such patients had been "evaluat[ed]."

30. ENZO personnel were told to select this code to avoid any delay or denial with respect to a claim submission to the patient's insurance carrier to falsely justify medical necessity and to expedite reimbursement. When Ms. McGuinness questioned why DEFENDANTS used ICD-10 code Z03.818, given that the testing performed at the universities and schools was exclusively for screening (not diagnostic) purposes, she was told to just follow direction and communicate the same to her group.

31. In addition, when screening asymptomatic individuals, ENZO occasionally performed testing using a technique known as "pooling" samples. This technique allows a lab to mix several samples together in a single batch or "pool" sample and then test the pooled sample with a diagnostic test. Because samples are pooled together under this method, ultimately fewer tests are run overall which lowers the cost to ENZO, yet DEFENDANTS bill the government for multiple tests.

32. ENZO's daily volume of "Covid screening" specimens totaled in the thousands. ENZO's large surveillance accounts include the following:

- SUNY Stony Brook – Stony Brook, New York
- SUNY New Paltz – New Paltz, New York
- SUNY Old Westbury – Old Westbury, New York
- Manhattan College – Riverdale, New York
- Bank Street School – New York, New York
- Spence School – New York, New York

- Cristo Rey New York High School – New York, New York
- The IDEAL School Manhattan – New York, New York
- Little Red School – New York, New York
- Manhattan College – Bronx, New York
- The Co-op School – Brooklyn, New York
- Resurrection Grammar School – Rye, New York

33. Bruce Dey, the former Corporate Vice President of Sales and Marketing at ENZO, estimates that the 2021 revenue from a few large State of New York University (SUNY) clients alone totaled more than \$15 million.

B. DEFENDANTS Waive Deductible Payments as a Kickback to Induce the Referral of Business

1. Co-Payments and Deductibles Are Essential Internal Controls for Payers

33. One of the principal purposes behind co-payment and deductible requirements is to make patients conscious of their medical services expenses, and thereby discourage the ordering and performance of unnecessary medical services. Co-payments and deductibles act as embedded internal controls for payors. There is no better mechanism to avoid unnecessary tests than requiring patients to pay a portion of the invoices for laboratory tests. Although co-payments and deductibles can be a financial burden to patients, service providers are required to make all necessary efforts to collect co-payments from patients, with limited exceptions.

34. Under Medicare, “waiver of deductibles and co-payments by charge-based providers, practitioners or suppliers is unlawful because it results in . . . false claims . . . [and] excessive utilization of items and services paid for by Medicare.”⁵

⁵ U.S. Dep’t Health & Hum. Servs., OIG Special Fraud Alerts (Dec. 19, 1994), *available at* <https://oig.hhs.gov/documents/physicians-resources/980/121994.pdf> [**Exhibit 3**].

35. As courts have recognized: “The ban against waiving the copayment is simply the corollary of the rule that a [health care provider] must report his true fee to [the plan]; if a [health care provider] intends to waive the copayment, it is fraudulent for him to report to [the plan] that his fee includes the copayment.” *Reynolds v. California Dental Service*, 200 Cal. App. 3d 590, 602 (1988).

2. Federal Law Prohibits the Provision of Anything of Value to Induce Referrals

36. The federal Anti-Kickback Statute provides for criminal penalties where an individual or entity

knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program

42 U.S.C. § 1320a-7b(b)(2)(A).

37. In October 1994, the Office of the Inspector General (“OIG”) issued a Special Fraud Alert addressing the question “How Does the Anti-Kickback Statute Relate to Arrangement for the Provision of Clinical Lab Services?” As an example of a situation giving rise to an inference of an illegal kickback, the Special Fraud Alert cited laboratories that waive charges to providers for lab tests of managed care patients (such as the deductibles and co-payments of patients for whom ENZO ran tests).⁶

38. The OIG has also stated that “[w]hen a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the

⁶ U.S. Dep’t Health & Hum. Servs., Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Oct. 1994), available at <https://oig.hhs.gov/documents/physicians-resources/980/121994.pdf> [Exhibit 3].

thing of value is offered to induce the referral of business.”⁷

39. The OIG has further made clear that “disguising remuneration for Federal referrals through offers or payments of inflated amounts for non-Federal business or simply by offering or paying remuneration for non-Federal referrals to ‘pull through’ the Federal business” “may violate the [A]nti-[K]ickback [S]tatute.”⁸ An OIG opinion letter issued in April of 2000 similarly indicates an anti-kickback “violation arises if the discount whatever its size is implicitly or explicitly tied to referrals of” government-funded business.⁹

40. In May 2008 the OIG issued interpretations of its prior guidance reaffirming that “when a laboratory offers or gives an item or service for free or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business.”¹⁰

41. In late 2018, as part of the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,” Congress passed the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), now codified as 18 U.S.C. § 220. The scope EKRA specifically extends to clinical laboratories of all types, regardless of involvement in opioid testing or not. EKRA prohibits the waiver of co-payments and deductibles. *See* 18 U.S.C. §§ 220(a), 220(e)(3)-24(b) (applying “with respect to services covered by a health care benefit program,” and defining “health care benefit program” as “any public or private plan or contract,

⁷ U.S. Dep’t of Health & Hum. Servs., OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Dec. 19, 1994), *available at* <https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html> [**Exhibit 3**].

⁸ U.S. Dep’t of Health & Hum. Servs., Advisory Opinion No. 00-8: Spectrum Housing, d/b/a Housing Referrals of Maine at 5 (2000), *available at* <https://oig.hhs.gov/documents/advisory-opinions/416/AO-00-08.pdf>.

⁹ U.S. Dep’t of Health & Hum. Servs. (April 20, 2000), *available at* <https://oig.hhs.gov/documents/other-guidance/917/amldiscount.htm#:~:text=An%20anti%2Dkickback%20statute%20violation,may%20provide%20evidence%20of%20intent>.

¹⁰ U.S. Dep’t of Health & Hum. Servs., Advisory Opinion No. 08-06 at 5 (2008), *available at* <https://oig.hhs.gov/documents/advisory-opinions/553/AO-08-06.pdf>.

affecting commerce, under which any medical benefit, item, or service is provided to any individual”). Like the AKS, EKRA is a criminal statute, giving rise to fines of up to \$200,000 per occurrence and up to 10 years of imprisonment.

3. New York’s Medicaid Regulations Prohibit the Provision of Anything of Value to Induce Referrals

42. Section 515.2 of the New York Administrative Code prohibits, *inter alia*, “offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for referring a client to a person for any medical care, services or supplies for which payment is claimed under the program.” N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2(b)(5)(iii).

43. Furthermore, waiving insurance deductibles and co-payments is illegal under New York Penal Law section 176.05. Section 176.05(2) makes it a “fraudulent insurance act” for a person to present a written statement as a part of, or in support of, an application for a claim of payment pursuant to a public or private health insurance policy, which he or she knows to “contain materially false information concerning any material fact thereto; or [] conceal, for the purpose of misleading, information concerning any fact material thereto.” N.Y. Penal Law § 176.05.

4. DEFENDANTS Routinely Violate Anti-Kickback Laws by Waiving Co-Payments and Deductibles

44. DEFENDANTS defrauded Medicare, Medicaid, and other government payors by routinely waiving patients’ co-payments and/or deductibles, which were effectively kickbacks to physicians who then referred substantial Medicare and other government business. DEFENDANTS thus presented to Medicare, and other government payors, claims for reimbursement of laboratory tests the referral of which was induced, in whole or in part, directly or indirectly, overtly or covertly, by the provision of kickbacks.

45. Each claim for payment submitted by DEFENDANTS, from approximately 2020 to the present, to Medicare, Medicaid, or HRSA that was referred to DEFENDANTS by a provider who received remuneration in the form of DEFENDANTS' waivers of co-payments and deductibles constitutes a false claim in violation of the False Claims Act. RELATOR is informed and believes that over this time period, DEFENDANTS have submitted tens of thousands of such claims for payment, and collected hundreds of millions of dollars from the government as a result of these kickbacks.

46. Emblem-GHI's Summary of Benefits and Coverage lists Emblem-GHI patient co-payments as \$50. *See Exhibit 4*. However, ENZO limited all deductible and co-payments to \$20 for all Emblem-GHI out-of-network patient insurance invoices. By routinely making these "adjustments," ENZO avoided the possibility of losing clients to the "participating" or "in-network" competitors. ENZO also facilitated the ability to sell new clients because their patients would not be disadvantaged financially by switching from an Emblem-GHI in-network lab, like Quest or LabCorp. With this illegal scheme, patients could reduce their co-payments 60% with ENZO rather than an in-network lab—a powerful incentive for physicians to refer Emblem-GHI patient specimens to ENZO.

47. DEFENDANTS' discounts (via the \$20 co-pay and deductible policy) are not disclosed to third party payors.

48. Attached as **Exhibit 5** are email requests from ENZO sales representatives requesting Emblem-GHI patients' deductibles and co-payments be written down to \$20.

49. Waiving all but \$20 of co-payments and deductibles is of great benefit to the doctors, as, among other things, it keeps patients happy as they are not coming out of pocket. In exchange for this benefit, doctors utilize ENZO for their Medicare and Medicaid patients. Knowing that the

waiver of co-payments and/or deductibles is a significant benefit that a physician can provide to his or her patients, DEFENDANTS promise physicians that ENZO will only seek to collect \$20 deductible or co-payments, as long as the physicians send business—including Medicare business—to ENZO.

50. Along similar lines, because Emblem-GHI's exclusive providers, both Quest Diagnostics and LabCorp, provided patients with one no-charge Pap test annually, ENZO matched this policy and provided free annual Pap tests for Emblem-GHI members. *See Exhibit 6.*

51. Since doctors generally prefer to use only one lab, this illegal scheme allowed ENZO to capture substantial “pull-through” Medicare, Medicaid and other revenue that ENZO would not have obtained but for this scheme. ENZO clients referring Emblem-GHI patient specimens include the following:

- E & G Healthcare – Staten Island, New York
- Premier OB/GYN – Staten Island, New York
- Michael Benson, M.D. – Staten Island, New York
- Medical Practice Associates – Staten Island, New York
- OBG Associates – Staten Island, New York
- Dr. Borislav Kheyson, M.D. – Staten Island, New York
- Dr. Scarfuri & Associates – Staten Island, New York
- Alan Friedman, M.D. – Staten Island & Brooklyn, New York
- Ahava Medical – Brooklyn, New York
- Bella Donna Medical – Brooklyn, New York
- Valerie Wells, M.D. – Manhattan, New York
- Saul Stromer, M.D. – Manhattan, New York

- Sabina Grochowski, M.D. – Manhattan, New York

52. Further, Emblem-GHI paid ENZO as an out-of-network lab much more than the in-network provider, relying on patients paying higher co-payments and deductibles to discourage patients using an out-of-network lab. Emblem-GHI's Summary of Benefits and Coverage explains that patients will pay the most for an out-of-network provider. *See Exhibit 4.*

53. Bill Wesnofske, ENZO's National Head of Strategic Markets, devised this scheme and tried to persuade Mr. Dey to implement this patient waiver policy with his sales team, but Mr. Dey refused, knowing the billing policy was illegal. After Mr. Dey's departure from ENZO, Mr. Wesnofske had conversations with members of Mr. Dey's former sales team who had begun reporting to him, asking them to make the programming changes in the ENZO ordering systems. They all refused. *See Exhibit 7.* The scheme was implemented despite these objections.

54. Mr. Wesnofske stated that ENZO had created a billing mechanism that will avoid the balance bill problem with "little noise" from clients already on the program. Also, he indicated to the sales group that this lenient billing policy should be shared with physicians and/or office staff to close new accounts.

55. This scheme is founded on the fact that physicians generally do not want to use multiple laboratories depending on the payor because, among other things, it creates more work for their offices. Labs "hook" out-of-network physician clients by offering to waive or cap patient deductible and co-payments at \$20. Although ENZO lost money on uncollected co-payments and deductibles, the higher out-of-network reimbursement and the profits it earned on the other referral business, including Medicare, Medicaid and HRSA more than made up the difference. While ENZO loses money on a given transaction by waiving patient co-pays and deductibles, the labs also generate tremendous revenue growth and profit from "pulling through" business from

Medicare and other government insurers, including Medicaid and HRSA. In the year ended July 31, 2020, Medicare alone accounted for 23% of ENZO's revenue. *See Exhibit 8.* RELATOR estimates Medicaid has accounted for approximately 5% of ENZO's revenue during the relevant time period.

56. DEFENDANTS' message is clear: physicians can order any test they want, even medically unnecessary tests because patients will only have to pay a \$20 co-pay or deductible. As a direct result of ENZO's waiver policy, ENZO's revenue grew significantly.

57. The fact that ENZO agrees to accept a fraction of the amount it costs to perform the tests when it bills patients makes clear that its scheme is an inducement to obtain the referral of profitable Medicare and other insurance paid business. There is no economic rationale for agreeing to lose money other than to use the waivers as "loss leaders" and inducement for additional business.

58. By partially waiving patient deductibles and co-payments, the physician is subject to diminished restraints on whether tests are medically necessary because their costs are substantially reduced for patients. Indeed, by minimizing the patient's financial stake in the transaction, DEFENDANTS have neutralized one of the market's inherent checks on frivolous treatment—individual monetary responsibility for the cost of care. DEFENDANTS thus undermined these safeguards by their routine waivers of patient deductibles and co-payments. With only a \$20 co-pay, there is a minimal financial barrier to physicians, which incentivizes ordering extra or expensive tests. Due to this scheme, insurers spend more than they otherwise would.

59. Likewise, ENZO's "Loss-leader / Pull-through" kickback scheme is predicated, in part, upon circumventing the nearly universal control used by managed care insurers—that it

will cost patients more to use an out-of-network provider.

60. Waiving co-payments and deductibles violates federal and state antikickback laws, including those set forth above. As described, this routine waiver of deductibles and co-payments constitutes illegal remuneration, designed by DEFENDANTS to “pull through” higher-paying Medicare and other government business to DEFENDANTS. DEFENDANTS violated the federal False Claims Act by charging Medicare for lab tests that were referred to DEFENDANTS by providers because of kickbacks offered to those providers by DEFENDANTS. Accordingly, DEFENDANTS’ practices were unlawful kickback schemes, strictly prohibited by Medicare statutes.

61. DEFENDANTS’ practices are independently unlawful as kickback schemes under New York’s Medicaid regulations and constitute “fraudulent insurance act[s]” under New York Penal Law section 176.05, and accordingly give rise to violations under the New York False Claims Act.

62. It is well known in the industry that DOJ has filed lawsuits against several companies for this very practice, alleging that it is an insurance fraud and kickback scheme. In *United States of America ex rel. Chris Riedel vs. Boston Heart Diagnostics Corporation*, federal Judge Reggie B. Walton ruled that an allegation that a defendant laboratory waived patients’ co-payments and deductibles, thereby providing a benefit to physicians, “sufficiently alleges how [a] purported waiver practice provided value to physicians; namely, by saving their time not spent on explaining copayment and deductible charges to patients and providing them an opportunity to market free laboratory testing.” 332 F. Supp. 3d 48, 66 (D.D.C. 2018).

63. Thus, at all times relevant hereto, DEFENDANTS knew that federal law prohibited their giving and/or receiving these kickbacks. Instead, DEFENDANTS certified, explicitly and implicitly, that each claim they submitted to Medicare would fully comply with all statutes and

regulations, including the anti-kickback provisions, and that as Medicare providers, they would comply with all pertinent statutes and regulations, including the anti-kickback provisions—which DEFENDANTS failed to do.

C. DEFENDANTS Use the Code for Rapid Testing Even When Rapid Testing Was Not Performed

64. Medicare, Medicaid, and HRSA pay a \$25 “add-on” where expedited testing is performed.¹¹ To qualify for expedited testing reimbursement, a laboratory must complete testing within “two calendar days of the specimen being collected.”¹²

65. ENZO routinely billed Medicare, Medicaid, HRSA and other payors for expedited testing using Healthcare Common Procedure Coding System (“HCPCS”) code U0005, even when expedited testing was not performed.

66. In fall 2021, a current ENZO senior executive told Chris Riedel that DEFENDANTS were engaging in “fraudulent billing” because HCPCS U0005 was billed on many tests even though the tests were not reported within forty-eight hours.

67. Mr. Dey confirmed that ENZO’s daily Covid-19 testing volumes often exceeded testing capacity and the excess specimens were referred to partner laboratories for testing where turn-around-time could be anywhere from three to seven days, or more.

68. One of ENZO’s primary reference laboratories, Baylor Genetics, is located in Houston, Texas. Patient specimens take more than two days just to arrive at the Baylor lab facility in Texas after being received at ENZO labs in Farmingdale, New York.

69. Despite not completing tests within the requisite two-day time frame, ENZO

¹¹ U.S. Ctr. Medicare & Medicaid Svcs., *CMS Rulings* (Jan. 1, 2021) at 6, *available at*: <https://www.cms.gov/files/document/cms-ruling-2020-1-r2.pdf>.

¹² *Id.*; U.S. Ctr. Medicare & Medicaid Svcs., *CMS Changes Medicare Payment to Support Faster COVID-19 Diagnostic Testing* (Oct. 15, 2021), *available at* <https://www.cms.gov/newsroom/press-releases/cms-changes-medicare-payment-support-faster-covid-19-diagnostic-testing>.

nonetheless billed HCPCS U0005 to obtain additional payment for the tests, including those referred to Baylor Genetics.

VI. DEFENDANTS KNOWINGLY VIOLATE THE CONNECTICUT FALSE CLAIMS ACT

70. DEFENDANTS violated Connecticut’s so-called “Most Favored Nation” regulation in which clinical laboratories should not seek payment from Connecticut Medicaid for services at a price that is higher than the lowest price the laboratory charges for the same or similar services from other third parties.” Conn. Agencies Regs. § 17b-262-649.¹³

71. According to the Connecticut Medicaid Fee Schedule Instructions, last updated March 30, 2022: “Providers must bill their lowest price charged or accepted from any other payer.”¹⁴

72. Connecticut’s “Most Favored Nation” regulation exists to ensure fair prices for the taxpayer funded Medicaid program.

73. In 2020, at a dinner at Cellini Restaurant in Manhattan, DEFENDANT RABBANI proudly announced to Bruce Dey and David Goldberg, ENZO Senior Vice President of Corporate Development, that he had a clear understanding of the sales function with respect to the Clinical Lab Division and intended to personally manage ENZO’s expansion into Connecticut, along with Kara Cannon. Mr. Dey explained to RABBANI that the expansion was a bad idea because of the numerous barriers to entry. ENZO would have to open a licensed laboratory location in the state to offer same day “Stat” lab services, expand in-network insurance contracts required to compete effectively, and open numerous Patient Service Centers (PSCs) for collection of patient specimens.

¹³ Conn. Off. Attorney Gen., *Attorney General Tong Announces \$4.8 Million Settlement with Redwood Toxicology Laboratory*, (Mar. 7, 2022) (reporting a settlement for alleged violations of Connecticut’s “Most Favored Nation” regulation by Redwood Toxicology Lab) [*See Exhibit 9*].

¹⁴ *See Exhibit 10*.

Even LabCorp, the second largest lab in the world, was unsuccessful in an attempted expansion into Connecticut because Quest was so prevalent in the state with strategic Health System partnerships, in-state regional lab acquisitions, and insurance contracts needed to cover the states patient population.

74. In response, Rabbani assured Dey that he had a plan for success, and that he was going to personally manage the expansion without using Dey's knowledge, experience, or sales team.

75. Rabbani then told Dey that Paul O'Brien, ENZO's then-Global Head of Human Resources, and Buddy Whitman, PhD, National Director of Clinical Services, were sent to Connecticut to expand Enzo's regional market presence through direct selling efforts to Urgent Care Centers. Dey believed that such selections made no sense, given the fact that neither O'Brien or Whitman had a track record in clinical lab sales. Rabbani reassured Dey and stated, in sum and substance: "don't worry, it will make sense to you, they are both grown-ups."

76. Dey eventually learned that Rabbani's plan was very simple: entice Urgent Care Centers with deeply discounted patient self-pay prices while charging the State of Connecticut far more.

77. **Exhibits 11 & 12** illustrate that rates charged to other payors that were substantially below the Connecticut Medicaid fee schedule. **Exhibit 11** shows relevant portions of the Connecticut Medicaid fee schedule. **Exhibit 12** shows ENZO invoices that were sent to AFC Urgent Care clients in Connecticut. The clients were billed directly because the AFC Urgent Care sites collected the lab fees from "self-pay" patients at the time of visit.

78. The table below, which reflects information in **Exhibits 11 & 12** shows instances where ENZO billed self-pay patients at rates under those set forth in the Connecticut Medicaid fee schedule.

CPT Code	Test	Fee Under Connecticut Fee Schedule	ENZO Charge to Self-Pay Patient
86480	Tuberculosis	\$59.19	\$27.00
86787	Chicken pox	\$12.31	\$4.79
86780	Syphilis	\$12.64	\$12.35
87186	Susceptibility studies, antimicrobial agent	\$8.26	\$5.94
86695	Herpes simplex type 1	\$12.60	\$11.00
86696	Herpes simplex type 2	\$18.48	\$11.00
87389	HIV-1 antigens with HIV-1 and HIV-2 antibodies	\$23.00	\$13.00
U0004	Covid-19	\$75.00	\$51.00

79. After enticing Urgent Care Centers with the discounted prices and contracting to providing laboratory services, ENZO would then submit electronic or paper invoices for clinical laboratory tests directly to Connecticut Medicaid for reimbursement.

80. Under the direction of DEFENDANTS Rabbani and Cannon, ENZO did not apply the same discounts when submitting invoices directly to the Connecticut Medicaid for reimbursement. Instead, DEFENDANTS submitted invoices for an amount that equaled or exceeded the maximum Medicaid reimbursement rate for each test performed.

81. Attached as **Exhibit 13** is a summary of the overcharges to Connecticut Medicaid for certain CPT codes. As shown, these overcharges averaged 82%.

82. When submitting claims for payment to Medicaid, ENZO represented that their charges complied with state Medicaid regulations. Those representations were false, in that ENZO was in fact charging far lower fees to other customers.

83. RELATOR is informed and believes, and thereon alleges, that under DEFENDANTS Rabbani's and Cannon's direction, ENZO submitted electronic or paper invoices to Connecticut Medicaid for clinical laboratory testing that reflected fees higher than those charged to other clients and the general public.

84. RELATOR is informed and believes, and thereon alleges, that at all times relevant hereto, DEFENDANTS Rabbani, Cannon and ENZO knew that their conduct would cause the Connecticut Medicaid to pay claims for the clinical laboratory tests based on fees higher than those charged to other clients and the general public. As a result of the foregoing, each claim for payment for each test that violated Conn. Agencies Regs. § 17b-262-649, was a false claim in violation of Connecticut False Claims Act.

85. The state of Connecticut has been damaged by DEFENDANTS' false claims.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

On Behalf of the United States

Federal False Claims Act, Presenting False Claims

31 U.S.C. § 3729(a)(1)(A)

(Against All Defendants)

86. RELATOR incorporates by reference and realleges each and every allegation of the preceding paragraphs of this Complaint as though fully set forth herein.

87. DEFENDANTS knowingly (as defined in 31 U.S.C. § 3729(b)(1)) presented or caused to be presented false claims for payment or approval to an officer or employee of the United States.

88. These claims were false because, *inter alia*:

a. DEFENDANTS submitted claims reimbursement for “diagnostic” tests even when the testing was done for surveillance purposes only;

b. DEFENDANTS waive patient co-payment and deductible obligations as a kickback in order to “pull through” government payments;

c. DEFENDANTS submitted claims for reimbursement for tests that were procured by means of, or otherwise involved, the payment of illegal kickbacks;

d. DEFENDANTS use the code for Covid-19 rapid testing even when rapid testing was not performed.

89. DEFENDANTS knowingly presented false records and statements, including but not limited to bills, invoices, requests for reimbursements, and records of services, in order to obtain payment or approval of charges by Medicare, Medicaid, and HRSA that were higher than they were permitted to claim or charge by applicable law.

90. The conduct of DEFENDANTS violated 31 U.S.C. § 3729(a)(1)(A) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

91. Wherefore RELATOR prays for relief as set forth below.

SECOND CAUSE OF ACTION
On Behalf of the United States
Federal False Claims Act, Making or Using False Records or Statements Material
to Payment or Approval of False Claims
31 U.S.C. § 3729(a)(1)(B)
(Against All Defendants)

92. RELATOR incorporates by reference and realleges each and every allegation of the preceding paragraphs of this Complaint as though fully set forth herein.

93. DEFENDANTS knowingly (as defined in 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

94. DEFENDANTS knowingly made, used, and/or caused to be made and used false

records and statements, including but not limited to bills, invoices, requests for reimbursement, and records of services, that were material to the payment or approval of charges by Medicare, Medicaid, and HRSA that were higher than they were permitted to claim or charge by applicable law.

95. The conduct of DEFENDANTS violated 31 U.S.C. § 3729(a)(1)(B) and was a substantial factor in causing the United States to sustain damages in an amount according to proof. The United States relied on DEFENDANTS' false representations in making payment on DEFENDANTS' claims.

96. Wherefore, RELATOR prays for relief as set forth below.

THIRD CAUSE OF ACTION
(In the Alternative)
On Behalf of the United States
Retention of Proceeds to Which Not Entitled
31 U.S.C. § 3729(a)(1)(G)
(Against All Defendants)

97. RELATOR incorporates by reference and realleges each and every allegation of the preceding paragraphs of this Complaint as though fully set forth herein.

98. In the alternative, DEFENDANTS knowingly made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

99. As discussed above, DEFENDANTS received far more money from the Medicare and Medicaid programs than it was entitled to. DEFENDANTS knew that it received more money than it was entitled to, and avoided its obligation to return the excess money to the Government.

100. The conduct of DEFENDANTS violated 31 U.S.C. § 3729(a)(1)(G) and was a substantial factor in causing the United States to sustain damages in an amount according to proof.

101. Wherefore, RELATOR prays for relief as set forth below.

FOURTH CAUSE OF ACTION
On Behalf of the State of New York
False Claims Act, Making or Using False Records or Statements
to Obtain Payment or Approval of False Claims
New York State Finance Law § 190(2)(b)
(Against All Defendants)

102. RELATOR incorporates by reference and realleges each and every allegation of the preceding paragraphs of this Complaint as though fully set forth herein.

103. This is a civil action brought by RELATOR, in the name of the State of New York, against Defendants, pursuant to the New York False Claims Act, N.Y. State Finance Law § 190(2)(b).

104. The State of New York and/or one of its agents contracted, directly or indirectly, with one or more carrier contractors in connection with the administration of Medicaid claims and/or claims under other state-funded plans in New York.

105. Medicaid managed care organizations directly or indirectly contracted with DEFENDANTS in connection with the administration of claims for reimbursement from Medicaid.

106. DEFENDANTS, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be causing to be presented, to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval under the New York Medicaid program, in violation of N.Y. State Finance Law § 189(1)(a).

107. DEFENDANTS, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or cause to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New York, in violation of N.Y. Finance Law § 189(1)(b).

108. The State of New York and/or its agencies or political subdivisions, unaware of the falsity of the claims and/or statements, paid, and may continue to pay for services that were never provided or are not medically reasonable and necessary for beneficiaries of health insurance programs funded by the State of New York or its agencies or political subdivisions.

109. As a result of DEFENDANTS' actions, the State of New York and/or its agencies or political subdivisions have been, and may continue to be, severely damaged.

FIFTH CAUSE OF ACTION

**On Behalf of the State of Connecticut
False Claims Act, Making or Using False Records or Statements
to Obtain Payment or Approval of False Claims Act
Conn. Gen. Stat. § 4-274, *et seq.*
(Against All Defendants)**

110. RELATOR incorporates by reference and realleges each and every allegation of the preceding paragraphs of this Complaint as though fully set forth herein.

111. This is a civil action brough by RELATOR, in the name of the State of New York, against Defendants, pursuant to the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274.

112. The State of Connecticut and/or one of its agents contracted, directly or indirectly, with one or more carrier contractors in connection with the administration of Medicaid claims and/or claims under other state-funded plans in Connecticut.

113. Medicaid managed care organizations directly or indirectly contracted with DEFENDANTS in connection with the administration of claims for reimbursement from Medicaid.

114. DEFENDANTS, in reckless disregard or deliberate ignorance of the truth or falsity

of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be causing to be presented, to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval under the Connecticut Medicaid program, in violation of Conn. Gen. Stat. § 4-275(a)(1).

115. DEFENDANTS, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or cause to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Connecticut, in violation of Conn. Gen. Stat. § 4-275(a)(2).

116. The State of Connecticut and/or its agencies or political subdivisions, unaware of the falsity of the claims and/or statements, paid, and may continue to pay for services that were never provided or are not medically reasonable and necessary for beneficiaries of health insurance programs funded by the State of Connecticut or its agencies or political subdivisions.

117. As a result of DEFENDANTS' actions, the State of Connecticut and/or its agencies or political subdivisions have been, and may continue to be, severely damaged.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, by and through the RELATOR, prays judgment in its favor and against DEFENDANTS as follows:

(1) That judgment be entered in favor of Plaintiffs UNITED STATES OF AMERICA, STATE OF NEW YORK, and STATE OF CONNECTICUT *ex rel.* Fraud Buster LLC, and against DEFENDANTS according to proof, damages in the amount of:

(a) Civil penalties as provided by statute for each false claim;

- (b) Triple the amount of damages sustained by the Government;
- (c) Recovery of costs;
- (d) Pre- and post-judgment interest;
- (e) Attorneys' fees;
- (f) Such other and further relief as the Court deems just and proper.

(2) Further, RELATOR, on its own behalf, requests that RELATOR receive such maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES OF AMERICA, STATE OF NEW YORK, and STATE OF CONNECTICUT plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. RELATOR requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

Respectfully Submitted,

Dated: September 6, 2022

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Attorneys for Relator Fraud Buster, LLC

IX. DEMAND FOR JURY TRIAL

Relator FRAUD BUSTER, LLC hereby demands a jury trial on all issues so triable.

Respectfully Submitted,

Dated: September 6, 2022

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